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In re Application of
Squirrell et al
Serial No. : 09/763,824
Filed : February 27, 2001
Attorney Ref No. : 1498-119

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.181, filed on April 15, 2005, to request the review and withdraw of the restriction requirement. The delay in acting on this petition is regretted.

BACKGROUND

A review of the file history shows that the application is the national stage filing under 35 U.S.C. 371 of PCT/ GB99/03538 filed 26 October 1999.

On 1/30/2004 a lack of unity requirement was made among the 30 original claims designating inventions corresponding to groups I through XVIII. Additionally, a further lack of unity designation was made for groups I through IV and X-XIII designating additional groups (a)-(i).

On 3/1/2004, applicants elected with traverse the subject matter of Group I and species Ia, drawn to a protein variant of *Photinus pyralis* luciferase (mutation at residue 214) having increased thermostability, a nucleic acid encoding therefore, a vector, a cell, a plant and the first claimed method of use, i.e. the use of a protein in a bioluminescent assay and a kit.

In response to the election, the examiner acknowledged the election of Group I(a), claims 1-5, 7-25 and 28-30, found the traversal non-persuasive and made the restriction requirement FINAL, in the paper mailed 12/15/2004.

A first office action on the merits was also mailed as a part of this same communication, in which claims 1-5, 7-8, 21-25 and 28-30 were rejected under 35 USC 112 1st and 2nd paragraphs, claims 1-5, 7-8 and 21 were rejected under 35 USC 101, claims 1, 2, 4, 5, 7 and 21-24 were rejected under 35 USC 102(b), claims 1, 2, 4, 5, 7, 21-24 and 28-30 were rejected under 35 USC 102(e), claim 25 was rejected under 35 USC 103 and claims 1-5, 7, 8 and 21-23 were rejected under double patenting.

In response to the Office action of 12/15/2004, applicants filed the instant petition, accompanying arguments and amendments of the claims on 4/15/2005.

DISCUSSION

The application, file history and petition under 37 C.F.R. 1.144, to request review of the restriction requirement has been considered.

Applicant's complete argument has been considered in full. Prior to the discussion of the merit of the petition, it is noted that those claims currently being examined are drawn to Group I(a) drawn to protein variants, nucleic acids encoding therefor, vectors, cells, first claimed method of use (i.e. a bioluminescent assay) and a kit.

This decision is in response to the Petition under 37 C.F.R. 1.144, filed on April 15, 2005, to request the reconsideration and withdrawal of the restriction requirement.

Applicants submit that the Examiner has artificially and without basis in the Rules, attempted to define as "special technical features of the claimed subject matter, the reference sources of the claimed variants. Applicants further submit that the examiner has asserted that 8 separate inventions are defined within Groups I- IX and that the plants of claim 26 define 37 separately patentable inventions.

Applicants submit that the only articulated basis for the Examiner's assertion of lack of unity invention is reliance on "Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions" and a conclusion that the claimed polypeptides are not regarded as being of similar nature because all alternatives do not share a common structure, providing no technical or scientific support for this conclusion. Applicants submit that the examiner admits that the claimed polypeptides "share a common property or activity."

Applicants further submit that the claimed polypeptides and other aspects of the claimed invention based thereon, share a common structure (i.e. "a significant structural element is shared by all of the alternatives"). In support of applicants "conclusion" with respect to common structure, applicants submit that the proteins of the claimed invention are a highly conserved group of proteins, obtainable from a limited number of sources and refer to Ye et al. to support applicants position stating that there are many motifs within the luciferase proteins that are common to all known luciferases. Finally, applicants note that even the U.S. Patent Office has

previously recognized that luciferases from different sources share a common structure based on the claims of U.S. Patent 6,132,983.

These arguments are not persuasive for the following reasons.

The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason(s):

As previously stated by the examiner, and recited by applicants in their submission, according to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, the requirement of a technical interrelationship and the same or corresponding special technical feature as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature and all alternatives have a common property or activity and a common structure is present i.e. a significant structural element is shared by all of the alternatives. While it has been admitted that the luciferase variants, nucleic acids, vectors and cells share a common property or activity, the polypeptides are **not** regarded as being of similar nature because all alternatives do not share a common structure. The argument that the claimed polypeptides and other aspects of the claimed invention based thereon, share a common structure (i.e. "a significant structural element is shared by all of the alternatives") is not persuasive because the mere 60% identity to a number of different luciferases from nine different species is not considered to define in any way a common structure. While applicants submit that the claimed polypeptides and other aspects of the claimed invention based thereon, share a common structure, applicants have not identified such a common structure that is shared by all of the various embodiments of the claims. While it is recognized that some of the encompassed inventions do share common structural motifs, all alternatives are not required to share a common structure. Moreover, even if a common structure were required by all the claimed inventions, the shared technical feature would not make a contribution over the prior art, in view of Ye et al, which teach that other known luciferases also share the common structure. Thus any shared technical feature is not considered special and unity is lacking. Thus the different subject inventions do not meet the requirement of a technical interrelationship and the same or corresponding special technical feature as defined in Rule 13.2.

Reference to the allowed claims of U.S. Patent 6,132,983, is acknowledged, however, the conclusions based on the allowed claims of another patent application, unrelated by priority lineage, are not justified and are not considered to be pertinent to the lack of unity determination for the present application. Applicant is reminded that restriction requirement or lack of unity determination is subject to the discretion of the examiner and thus what is done in one application is not necessarily relevant to another application.

Finally, with respect to the assertion of the lack of a corresponding technical feature for the plants of claim 26, Groups X through XVIII, and the subject inventions of Groups I through IX, this requirement has been withdrawn and claim 56 (previous claim 26) is now grouped with

each of groups I-IX and groups (a)-(i). Thus, the plants of claim 56 will be examined to the extent that they depend on the cells of claim 55 and the subject matter of the elected group.

DECISION

For these reasons, the petition under 37 C.F.R. 1.144, to request to withdraw of the lack of unity determination is **GRANTED-IN-PART**. As discussed above, the request for the rejoinder of Groups X through XVIII is **GRANTED** and the request for the rejoinder of Groups I-IX is **DENIED**.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

The application will be forwarded to the examiner to take appropriate action as a result of this petition decision and to consider the amendments and arguments filed by applicants on 4/15/2005.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-273-8300.



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